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\*Admitted only in Maryland  
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March 7, 2006

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Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**Art Unit 1614**

**Mail Stop Amendment**

Re: U.S. Utility Patent Application  
Application No. 10/518,618; § 371 Date: December 22, 2004  
For: **Conjugates Comprising an NSAID and a Sugar and Uses Thereof**  
Inventors: **Holick et al.**  
Our Ref: 2317.0430001/RWE

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement Filing Under 37 C.F.R. § 1.97(b);
2. Information Disclosure Statement Form PTO/SB/08A (2 sheets);
3. Information Disclosure Statement Form PTO/SB/08B (1 sheet);
4. Copies of eight (8) references (Documents **FP1-FP4** and **NPL1-NPL4**);
5. First Supplemental Information Disclosure Statement;
6. First Supplemental Information Disclosure Statement Form PTO/SB/08A (2 sheets);
7. First Supplemental Information Disclosure Statement Form PTO/SB/08B (1 sheet);
8. Copies of six (6) references (Documents **NPL5-NPL10**); and
9. Return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are

Commissioner for Patents  
March 7, 2006  
Page 2

necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

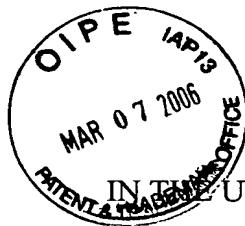
Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Robert W. Esmond  
Attorney for Applicants  
Registration No. 32,893

RWE/dab  
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Enclosures



UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Holick *et al.*

Appl. No.: 10/518,618

§ 371 Date: December 22, 2004

For: **Conjugates Comprising an NSAID  
and a Sugar and Uses Thereof**

Confirmation No.: 8983

Art Unit: 1614

Examiner: Kim, Vickie Y.

Atty. Docket: 2317.0430001/RWE

**Information Disclosure Statement Filing Under 37 C.F.R. § 1.97(b)**

*Mail Stop Amendment*

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Forms PTO/SB/08A and PTO/SB/08B are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of documents **FP1-FP4** and **NPL1-NPL4** are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), no copies of U.S. patents and patent application publications cited on the attached Form PTO/SB/08A are submitted.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return copies of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

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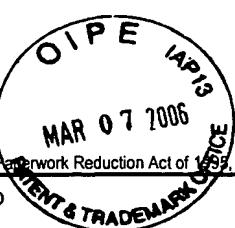


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Date: 3/7/06

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Substitute for form 1449/PTO				<b>Complete if Known</b>	
				Application Number	10/518,618
				§ 371 Date	December 22, 2004
				First Named Inventor	Holick, Michael F.
				Art Unit	1614
				Examiner Name	Vickie Y. Kim
Sheet	1	of	2	Attorney Docket Number	2317.0430001/RWE

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)	MM-DD-YYYY		
US1	US 4,599,418		07-08-1986	Irikura <i>et al.</i>	
US2	US 4,774,230		09-27-1988	Tuttle <i>et al.</i>	
US3	US 5,051,448		09-24-1991	Shashoua	
US4	US 5,179,093		01-12-1993	Afonso <i>et al.</i>	
US5	US 5,412,083		05-02-1995	Giese <i>et al.</i>	
US6	US 5,436,253		07-25-1995	Rinaldi <i>et al.</i>	
US7	US 5,436,325		07-25-1995	Johnson <i>et al.</i>	
US8	US 5,466,681		11-14-1995	Krivan <i>et al.</i>	
US9	US 5,508,392		04-16-1996	Holick, M.F.	
US10	US 5,518,738		05-21-1996	Eickhoff <i>et al.</i>	
US11	US 5,633,357		05-27-1997	Tius <i>et al.</i>	
US12	US 5,707,605		01-13-1998	Meade <i>et al.</i>	
US13	US 6,074,625		06-13-2000	Hawthorne <i>et al.</i>	
US14	US 6,214,345 B1		04-10-2001	Firestone <i>et al.</i>	
US15	US 6,277,818 B1		08-21-2001	Mazar <i>et al.</i>	
US16	US 6,548,484 B1		04-15-2003	Christian, S.T.	
US17	US 2001/0041676 A1		11-15-2001	Holick <i>et al.</i>	
US18	US 2002/0002140 A1		01-03-2002	Holick <i>et al.</i>	
US19	US 2003/0216328 A1		11-20-2003	Holick <i>et al.</i>	
US20	US 2004/0087559 A1		05-06-2004	Schwartz <i>et al.</i>	

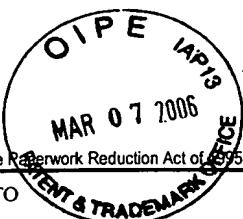
FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)			
FP1	GB 1,029,222		05-11-1966	Beecham Group Limited	
FP2	WO 92/18005 A1		10-29-1992	National Institutes of Health	
FP3	WO 94/14411 A1		07-07-1994	Holick	
FP4	WO 96/03995 A1		02-15-1996	Holick	

Examiner Signature	Date Considered
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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

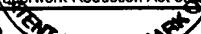
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 <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>		<b>Complete if Known</b>	
Sheet	2	of	2
		Attorney Docket Number	2317.0430001/RWE
		Application Number	10/518,618
		§ 371 Date	December 22, 2004
		First Named Inventor	Holick, Michael F.
		Art Unit	1614
		Examiner Name	Vickie Y. Kim

## **U.S. PATENT DOCUMENTS**

## FOREIGN PATENT DOCUMENTS

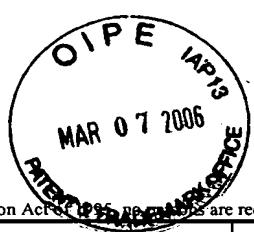
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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
*(Use as many sheets as necessary)*

Sheet

1

of

1

**Complete if Known**

Application Number	10/518,618
§ 371 Date	December 22, 2004
First Named Inventor	Holick, Michael F.
Art Unit	1614
Examiner Name	Vickie Y. Kim
Attorney Docket Number	2317.0430001/RWE

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	NPL1	Ali, S.A., et al., "Improving the Tumor Retention of Radioiodinated Antibody: Aryl Carbohydrate Adducts," <i>Canc. Res. (Suppl.)</i> 50:783S-788S, American Association for Cancer Research (1990)	
	NPL2	Database STN Easy, Accession No. 2001:136552, Haubner et al. (February 2001)	
	NPL3	Murakami, K., et al., "Excretion of New Quinolones and their Glucuronide Conjugates into Human Bile," <i>Drugs 49 (Suppl. 2)</i> :331-332, Adis International Limited (1995)	
	NPL4	Strobel, J.L., et al., " <sup>125</sup> I-Glycoconjugate Labels for Identifying Sites of Protein Catabolism <i>in Vivo</i> : Effect of Structure and Chemistry of Coupling to Protein on Label Entrapment in Cells after Protein Degradation," <i>Arch. Biochem. And Biophys.</i> 240:635-645, Academic Press, Inc. (1985)	

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Examiner Signature	Date Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Confirmation No.: 8983
Holick <i>et al.</i>	Art Unit: 1614
Appl. No.: 10/518,618	Examiner: Kim, Vickie Y.
§ 371 Date: December 22, 2004	Atty. Docket: 2317.0430001/RWE
<b>For: Conjugates Comprising an NSAID and a Sugar and Uses Thereof</b>	

**First Supplemental Information Disclosure Statement**

***Mail Stop Amendment***

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying IDS Forms are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this First Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Information Disclosure Statement filed concurrently herewith, in connection with the above-captioned application. Copies of documents **NPL5-NPL10** are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), no copies of U.S. patents and patent application publications cited on the attached IDS Forms are submitted.

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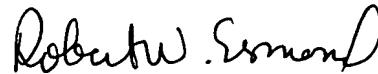
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Robert W. Esmond  
Attorney for Applicants  
Registration No. 32,893

Date: 3/7/06

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Substitute for form 1449/PTO				<b>Complete if Known</b>	
<b>FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				Application Number	10/518,618
				§ 371 Date	December 22, 2004
				First Named Inventor	Michael F. Holick
				Art Unit	1614
				Examiner Name	Kim, Vickie Y.
Sheet	1	of	2	Attorney Docket Number	2317.0430001/RWE/BSA

<b>U.S. PATENT DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)	MM-DD-YYYY		
	US25	4,292,425	09-29-1981	Buckler <i>et al.</i>	
	US26	4,261,974	04-14-1981	Buckler <i>et al.</i>	
	US27	4,595,695	06-17-1986	Ladkani <i>et al.</i>	
	US28	4,751,219	06-14-1988	Kempen, H.J.M.	
	US29	4,855,463	08-08-1989	Barua <i>et al.</i>	
	US30	4,894,476	01-16-1990	Butler <i>et al.</i>	
	US31	4,897,382	01-30-1990	della Valle <i>et al.</i>	
	US32	4,939,174	07-03-1990	Shashoua, V.E.	
	US33	5,114,976	05-19-1992	Norden, M.J.	
	US34	5,162,573	11-10-1992	Chiesi <i>et al.</i>	
	US35	5,340,803	08-23-1994	Rubin, D.	
	US36	5,440,023	08-08-1995	Cheng <i>et al.</i>	
	US37	5,506,224	04-09-1996	della Valle <i>et al.</i>	
	US38	5,559,235	08-24-1996	Luzzio <i>et al.</i>	
	US39	5,561,119	10-01-1996	Jacquesy <i>et al.</i>	
	US40	5,599,953	02-04-1997	Curley, Jr. <i>et al.</i>	
	US41	5,677,286	10-14-1997	Shull <i>et al.</i>	
	US42	5,679,667	10-21-1997	Della Valle <i>et al.</i>	
	US43	5,707,663	01-13-1998	Ayer <i>et al.</i>	
	US44	5,760,072	06-02-1998	de Bont <i>et al.</i>	

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		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	MM-DD-YYYY		T <sup>6</sup>
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	FP6				
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	FP13				

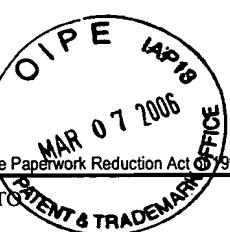
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Examiner Signature	Date Considered
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STATEMENT BY APPLICANT**

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Application Number	10/518,618
§ 371 Date	December 22, 2004
First Named Inventor	Michael F. Holick
Art Unit	1614
Examiner Name	Kim, Vickie Y.

Attorney Docket Number 2317.0430001/RWE/BSA

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if Known)	MM-DD-YYYY		
	US45	5,808,111	09-15-1998	Curley, Jr., R.W.	
	US46	5,827,819	10-27-1998	Yatvin <i>et al.</i>	
	US47	5,977,326	11-02-1999	Scheinmann <i>et al.</i>	
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	US50	6,043,367	03-28-2000	Roffler <i>et al.</i>	
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	US61	US 2005/0130908 A1	06-16-2005	Holick <i>et al.</i>	
	US62				
	US63				
	US64				

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	MM-DD-YYYY			
	FP14					
	FP15					
	FP16					
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	FP18					
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	FP20					
	FP21					
	FP22					

Examiner Signature	Date Considered
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Attorney Docket Number

2317.0430001/RWE/BSA

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	NPL5	Fernández, C. <i>et al.</i> , "Synthesis and biological studies of glycosyl dopamine derivatives as potential antiparkinsonian agents," <i>Carbohydrate Research</i> 327:353-365, Elsevier Science Ltd. (2000)	
	NPL6	Lemberber, L., <i>et al.</i> , "Fluoxetine: Clinical Pharmacology and Physiologic Disposition," <i>J. Clin. Psychiatry</i> 46(3):14-19, Physicians Postgraduate Press (March 1985)	
	NPL7	Maryanoff, B.E. <i>et al.</i> , "Anticonvulsant O-Alkyl Sulfamates. 2,3,4,5-Bis-O-(1-methylethylidene)-β-D-fructopyranose Sulfamate and Related Compounds," <i>J. Med. Chem.</i> 30:880-887, American Chemical Society (1987)	
	NPL8	Maryanoff, B.E. <i>et al.</i> , "Structure-Activity Studies on Anticonvulsant Sugar Sulfamates Related to Topiramate. Enhanced Potency with Cyclic Sulfate Derivatives," <i>J. Med. Chem.</i> 41:1315-1343, American Chemical Society (1998)	
	NPL9	Remington's Pharmaceutical Sciences, Osol, A., <i>et al.</i> , eds., 16 <sup>th</sup> edition, Chapter 36, pp. 677-678, Philadelphia College of Pharmacy and Science (1980)	
	NPL10	Rowley, M. <i>et al.</i> , "Effect of Plasma Protein Binding on in Vivo Activity and Brain Penetration of Glycine/NMDA Receptor Antagonists," <i>J. Med. Chem.</i> 40:4053-4068, American Chemical Society (1997)	
	NPL11		
	NPL12		
	NPL13		
	NPL14		

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Examiner Signature	Date Considered
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